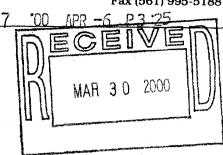


6111 Broken Sound Parkway NW Boca Raton, FL 33487-3693 (561) 241-9400 Fax (561) 995-5188

March 18, 2000

Food and Drug Administration Office of Special Nutritionals (HFS-450) Center for Food Safety and Applied Nutrition 200 C Street, SW Washington, DC 20204



Dear Sirs:

Notice is hereby given that Rexall Sundown, Inc. ("Sundown") located at 6111 Broken Sound Parkway, N.W., Boca Raton, Florida 33487 has marketed a dietary supplement under the Thompson, SDV Vitamins, Rexall and Sundown brand names bearing the following statement(s) on the label and/or in the labeling:

<u>Kava Kava (Thompson)</u>: [It] promotes a calming sense of well-being. For centuries, Pacific islanders have used [it] for its unique ability to evoke a feeling of calm contentment. [It] combines Kava Kava extract with an Advanced Formula Blend of the whole herbs Hops, Chamomile and Passionflower to help promote a calming and soothing sense of well-being.

Kava Kava (Rexall): [It] promotes a calming and soothing sense of well-being. Kava Kava is native to the South Pacific islands. Island people have been using Kava for centuries for its natural calming and soothing effects.

SDV Kava Kava Preferred<sup>TM</sup> (SDV): [It] is an advanced formula containing a select combination of Kava Kava, Passionflower, Hops and Chamomile which helps promote a calming and soothing sense of well-being.

<u>Kava Kava (Sundown):</u> [For] calm well-being. [It] is nature's "stress buster." Used for centuries in traditional ceremonies of the South Pacific, kava relaxes your muscles and calms your emotions while actually sharpening the senses. Research suggests that compounds found in kava root help to soothe everyday anxiety and promote a general feeling of well-being.

<u>Kava Kava XTRA (Sundown)</u>: [For] calm well-being. [It] is nature's "stress buster." Used for centuries in traditional ceremonies of the South Pacific, kava relaxes your muscles and calms your emotions while actually sharpening the senses. Research suggests that compounds found in kava root help to soothe everyday anxiety and promote a general feeling of well-being. Sundown's Kava Kava XTRA keeps you calm and mentally sharp while promoting a sense of peace and contentment.

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The undersigned certifies that the information contained in this notice is complete and accurate and that Rexall Sundown, Inc. has substantiation that the statement is truthful and not misleading. Pursuant to § 101.93 (a)(1), two copies of this notification are enclosed.

Sincerely,

Phosau Sum ande

Deborah Shur Trinker Vice President of Regulatory Affairs and Assistant General Counsel

Enclosure